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Office of Research Integrity

NEWSLETTER

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research.

IN THIS ISSUE

RCR Resource Program to Make Nine Awards

Nine awards will be made this summer in the RCR Resource Development Program to support creation of resources addressing peer review, publication practices, data management, research misconduct, cultural diversity, assessment and evaluation, and lab management.

With these awards, the program has supported 49 projects since its establishment in 2002 to facilitate the development of RCR resources by the research community for the research community. Twenty completed resources are posted on the ORI web site at *http://ori.hhs.gov/education/rcr_resources.shtml*.

See Request, page 3

RRI Program RFA Contains Changes

Several changes have been made to the new request for applications (RFA) for the Research on Research Integrity (RRI) Program including the application deadline, areas of interest, and review and grant management processes.

The application deadline is two months earlier, September 16, 2005, than usual. An applicant may request a project period of up to 2 years and a budget for direct costs not to exceed $175,000 per year.

The new RFA is posted on the ORI home page at http://ori.hhs.gov.

See RRI, page 2

ORI Producing Aids for Transition to New Reg

ORI is developing a model addendum that institutions may use to amend their existing policy on handling allegations of research misconduct to bring them into compliance with the new research misconduct regulation that became effective on June 16, 2005.

Other aids under development include a review form that will enable institutions to evaluate their policy for compliance with the new regulation and a Q&A sheet. The ORI Model Policy and Procedures will also be revised.

ORI may use video conferencing to promote a dialogue with institutions

See New, page 2

Researcher Facing Sentencing Hearing

A tenured research professor who will be sentenced later this year after pleading guilty in a U. S. District Court to making material false statements in a federal research grant application has already had civil and administrative actions imposed upon him.

At the upcoming arraignment, Eric T. Poehlman, Ph.D., faces up to five years imprisonment, but he has requested a more lenient sentence based upon his cooperation with authorities and his acceptance of responsibility. The Justice Department has agreed to take no position on the request.

See First, page 2

RRI Researchers Publish In Major Journals

Since investigators supported by the Research on Research Integrity (RRI) Program began publishing their findings in 2003, their work has appeared in 10 publications including several major biomedical journals.

Fourteen manuscripts have been published including two in the *British Medical Journal*, and one each in the *New England Journal of Medicine*, the J*ournal of the American Medical Association*, and *Nature*. The RRI Program started in 2001.

Other publications are in *Academic Medicine,Contemporary Clinical Trials, Accountability in Research, Journal of Research Administration, Health Affairs,* and *Minnesota Medicine*.

The most recent publications are listed on the ORI home page in the Research Results section. Citations to all publications may be found at *http://ori.hhs.gov/research/rri_publications.shtml*.

New Regulation *(from page 1)*

on the implementation of the new regulation.

"We plan to complete all of the documents by early next year, but we will post them on the ORI web site as they become available," Chris Pascal, Director, ORI, said. "We want to make the transition to the new regulation as smooth as possible."

The final rule was published in the *Federal Register* on May 17, 2005 and is available on the ORI home page.

RRI Program Expands Areas of Interest *(from page 1)*

Two new areas of interest are included in the RFA: (1) best practices related to data collection, storage, and sharing; data selection, interpretation and reporting; the use of statistics in data interpretation and reporting significant results; assigning authorship; mentoring, and collaborative research, and (2) economic, policy and scientific impacts of research misconduct and questionable research practices.

Applications will be reviewed by the Center for Scientific Review (CSR), National Institutes of Health. Grant management will be handled by the National Institute of Nursing Research (NINR).

"ORI is very grateful to the National Institute of Neurological Disorders and Stroke (NINDS) for the essential review and grant management support it provided during the formative years of the program," said Dr. Mary Scheetz, Director, ORI extramural research program. "We also are extremely pleased that CSR and NINR have volunteered to take over the review and grant management responsibilities for the program."

Besides NINR, NINDS and ORI, participating organizations in the RFA are the National Institute on Drug Abuse and the Agency for Healthcare Research and Quality.

First Researcher Debarred for Life *(from page 1)*

Two other researchers supported by the Public Health Service have faced criminal charges stemming from research misconduct. Stephen E. Bruening, Ph.D., was sentenced to 60 days in jail and five years probation in 1989; Pat J. Palmer was sentenced to one-year supervised probation and a suspended 180-day jail stay in 2004.

An investigation by the University of Vermont, the Justice Department and ORI found that Dr. Poehlman had falsified and fabricated data in numerous federal research grant applications that generated about $2.9 million in funding for his research over a 10 year period.

Dr. Poehlman has already agreed to pay $180,000 to settle a civil complaint related to the false grant applications. He also will pay $16,000 in attorney fees to counsel for Walter F. DeNino, a research assistant who made the allegation of research misconduct.

Dr. Poehlman is the first researcher supported by the Public Health Service (PHS) to be debarred for life from receiving federal government funds and from serving the PHS in an advisory capacity. He also was required to retract or correct 10 articles.

The *Federal Register* notice and other documents related to the case are on the ORI web site at *http://ori.hhs.gov/misconduct/cases/poehlman.shtml*.

Can Colleagues Understand Your Recorded Data?

Request for RCR Resource Proposals Coming This Fall *(from page 1)*

"We had the lowest number of proposals coupled with the highest funding rate in the fourth round," Loc Nguyen-Khoa, Director, RCR Resource Development Program, said. "Fifteen proposals were submitted; 9 were recommended for support. The funding rate is 60 percent." Award abstracts are posted on the ORI web site at *http://ori.hhs.gov/education/rdp.shtml*.

A new request for proposals (RFP) will be issued this fall. Submission deadline will be February 24, 2006. The RFP will be posted on the ORI home page and in the *NIH Guide for Grants and Contracts*. For information on the program contact Mr. Nguyen-Khoa at *LNguyen-Khoa@osophs.dhhs.gov*.

Project titles, project directors, and institutions receiving the awards follow:

- *Data Acquisition, Retention, Storage, Custody, Sharing, Ownership, Interpretation and Reporting*. Neil Mehta, Cleveland Clinic Foundation.
- *Utilizing Video Vignettes and Decision Tree Technology to Promote Responsible Conduct in Research Data Acquisition, Management, Sharing and Ownership.* Derina S. Samuel, Syracuse University Graduate School.
- *Promoting Responsible Peer Review and Publishing Through Interactive E-Learning Experience*. Murali Krishnamurthi, Northern Illinois University
- *Peer Review Tool – Sample Size Determination for Experimental Studies*. Min Qi Wang, University of Maryland - College Park.
- *Development of a Web-based Educational Intervention on Research Misconduct*. Melissa Proll, The University of Texas Health Science Center - Houston.
- *Mentorship for Multi-cultural Research Populations.* Wayne Patterson, Howard University.
- *Baseline RCR Testing Program*. Elizabeth Heitman, Vanderbilt University Medical School.
- *Development and Testing of a Web-based Tutorial for Program Evaluation of RCR Education*. Rebecca C. Henry, Michigan State University.
- *Lab Management: Training and Education for the Principal Investigator and Associated Technical Personnel.* Dan Nordquist, Washington State University.

Award abstracts are posted at *http://ori.hhs.gov/education/rdp.shtml*.

Third RCR Expo Slated; Register by August 31

Institutions and organizations that desire to exhibit their RCR instructional materials, web sites or programs during the third RCR Expo must register with ORI by August 31, 2005 because of limited space.

The RCR Expo will be held October 17-18, 2005 in the Midwest Airlines Center in Milwaukee in conjunction with the annual meeting of the Society of Research Administrators (SRA) International attended by over 1400 research administrators.

"The RCR Expo is open to any institution or organization that is willing to share its RCR resources with others," Loc Nguyen-Khoa, Director, RCR Resource Development Program, ORI, said. "The expo provides an excellent opportunity to learn about educational resources and tools that can enhance an RCR educational program at any institution."

ORI will provide 25 free spaces to qualified exhibitors. Besides floor space, exhibitors will be provided with a table, a chair and electricity at no cost, but they will have to furnish their own computers, projectors and other display technology. No special security will be provided, so exhibitors will have to monitor their own displays.

Exhibits may focus on one or more of the RCR core areas or on other areas deemed related to responsible conduct of research. Products related to the administration of RCR programs are included. such as train the trainer programs, and databases for tracking completion of instruction. The RCR core areas are (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct, and (9) conflict of interest and commitment.

Contact Loc Nguyen-Khoa at *LNguyen-Khoa@osophs.dhhs.gov*. For more information about the SRA International annual meeting, visit *http://www.srainternational.org*.

ORI to Contract with CITI to Create an RCR Course

ORI will contract with the Collaborative Institutional Training Initiative (CITI) Program to develop a responsible conduct of research (RCR) course that will be available to individuals, institutions and organizations free of charge.

The RCR course will cover seven of the nine core RCR instructional areas: data acquisition, management, sharing and ownership; mentor/trainee relationships; publication practices and responsible authorship, peer review, collaborative science, research misconduct, and conflict of interest. Courses on human subject protections and animal welfare are available through the ORI web site and elsewhere. The course is expected to be available in late 2006.

CITI was founded in 2000 by a consortium of investigators, administrators, and bioethicists to provide web based instruction in human subjects protection. Over 450 organizations worldwide are CITI members. Over 180,000 persons have taken its human subjects protection course.

Any organization will be able to participate in the CITI-RCR program at no cost. Upon request CITI will customize courses for institutions to fit the needs of learner groups in the various sciences at the undergraduate, graduate, postdocs, and faculty levels. Individual learners will also be able to register for an RCR course at the CITI website (*www.citiprogram.org*).

An RCR Developers Group will be created to monitor the course and conduct semi-annual reviews. CITI will offer CME or CEU credits through the University of Miami Office of Continuing Medical Education.

The CITI-RCR Program will provide course site administration, technical support for administrators and a help desk for learners. Instructional records will be maintained on a secure CITI Program dedicated server. Institutional administrators will be able to download instructional records for their learners from the course site.

When learners complete the institutionally prescribed course, they will receive a completion report (transcript) describing the curriculum completed. Successful completion is based on attaining a score (determined by the institution) on the quizzes associated with each module.

Use of ORI Website Shows Big Increases

The number of visits and visitors to the ORI website dramatically increased between FY 2003 and FY 2004 according to WebStats.

The number of visits almost tripled, increasing from 74,602 to 219,525. The number of unique visitors more than doubled from 38,359 to 92,076 and the number of repeat visitors more than tripled from 7,855 to 24,490. The average visit length increased from 17 to 18 minutes.

Besides the United States, the website was accessed by visitors from Australia, Canada, China, France, Germany, Hong Kong, India, Israel, Italy, Japan, Malaysia, the Netherlands, the Philippines, Poland, Singapore, South Korea, Sweden, and the United Kingdom.

ORI Intro to RCR Marks Anniversary

The *ORI Introduction to the Responsible Conduct of Research* has had a successful first year, selling over 5,000 copies and being translated into Japanese and Chinese. Another 1,000 copies were downloaded from the ORI web site.

A Japanese translation of the booklet was published earlier this year by Maruzen Co., Ltd., Tokyo. A Chinese translation is in preparation.

ORI has ordered the printing of another 5,000 copies of the booklet to ensure an adequate supply for the fall semester. These copies may be purchased from the Government Printing Office at *http://bookstore.gpo.gov*. Cost is $14.00 per copy: a 25 percent discount is offered on purchases of every 100 copies sent to the same address.

The publication is also available for on-line reading or downloading on the ORI home page at *http://ori.hhs.gov*.

The 165-page booklet, written by Nicholas H. Steneck, University of Michigan, with illustrations by David Zinn, Ann Arbor, introduces the reader to the nine RCR core instructional areas in four sections that follow the research process from inception to planning, conducting, reporting and reviewing. The publication features case studies, text-box inserts, discussion questions, and electronic and print resources.

NEW PHONE NUMBERS

ORI phone numbers were changed in May 2005. Fax numbers remain the same.
See listing on page 12.

Assurance Program Managerial Change; Brown Retires

Doug Brown, Assurance Program Manager, will become a country gentlemen on July 23, 2005 when he retires to an outdoor life on his farm in southern Virginia where deer, turkey and bear freely roam and a bubbling brook entices quiet contemplation. He will be replaced by Randi Freedman who has been working in the program for the past year to facilitate a smooth managerial transition.

Mr. Brown has been associated with the Assurance Program since he joined ORI as a program assistant in October 1992 rising to the managerial post in June 2002. During his tenure, the assurance program underwent considerable evolution culminating in the transition to electronic administration.

"I am sure that research organizations and funding agencies appreciate the timely, accurate, reliable, courteous and dependable service Doug provided to them over the years," Larry Rhoades, Director, Division of Education and Integrity, ORI, said. "I certainly do. Running the assurance program is a very demanding job."

Ms. Freedman has held positions throughout ORI since she was hired more than 11 years ago as a program specialist in the Division of Investigative Oversight. Subsequently, she was promoted to information technology specialist in the Office of the Director and eventually was transferred to DEI where webmaster duties were added to her repetoire. She is pursuing a degree in business administration in the evenings.

8 RCR Awards Made to Academic Societies

Eight awards were made this summer by the RCR Program for Academic Societies to facilitate the institutionalization of infrastructure and activities within academic societies that will promote the responsible conduct of research by their members.

The program, a collaboration between the Association of American Medical Colleges and ORI, has supported 32 projects by 27 academic societies in its first three years. Submission deadlines for the next round of applications are November 11, 2005 and March 3, 2006. See ORI home page for RFA.

Any academic society whose members conduct biomedical or behavioral research supported by the U. S. Public Health Service is eligible to apply. The program offers awards up to $50,000.

The purpose of the awards is to provide funds to academic societies to specifically address some, or all, of the nine core components of the responsible conduct of research, and to mainstream or institutionalize RCR infrastructure, activities, and educational programs into the culture of the societies and disciplines.

Of special interest are projects focused on developing guidelines, standards, policies, publications (including RCR articles in journals, newsletters, and on society web sites), committees, annual conferences, core competencies, curricula, and other resources related to the core RCR components.

For further information contact Tony Mazzaschi, AAMC, at *tmazzaschi@aamc.org* or at 202-828-0059. Award abstracts are posted on the ORI web site at *http://ori.hhs.gov/education/pas.shtml*.

Academic societies receiving awards and project titles follow:

- **Association of Rheumatology Health Professionals.** "Responsible Data Management in Research: Getting It Right the First Time."
- **American Speech-Language-Hearing Association.** "Enhancing Research Integrity: The Publication Process."
- **Association of Academic Physiatrists.** "An Enduring Multidisciplinary Curriculum for Responsible Conduct of Rehabilitation Research."
- **AcademyHealth.** "Promoting AcademyHealth's Ethical Guidelines for Health Services Research."
- **Society for Academic Continuing Medical Education.** "Improving the Informed Consent Process."
- **American Academy of Family Physicians.** "Continuing Medical Education and Conflicts of Interest."
- **Public Health Leadership Society.** "Public Health Research and the Public Health Code of Ethics."
- **Association of Anatomy, Cell Biology and Neurology Chairs.** "Nobel Roundtable Discussion on the Impact of Large Interdisciplinary and Inter-institutional Consortia on Conflict of Interest and Scientific Misconduct."

NRC, Sigma Xi Reports Address Plight of Postdoctoral Fellows

Reports issued by the National Research Council (NRC) and Sigma Xi continue to spotlight the plight of postdocs in the biomedical research community and call upon universities and the National Institutes of Health to address their training needs and working conditions.

The NRC report, *Bridges to Independence: Fostering the Independence of New Investigators in Biomedical Research*, is available at *http://books.nap.edu/catalog/11249.html*. The Sigma Xi report, *Doctors Without Orders*, is available at *http://postdoc.sigmaxi.org/results/*.

The NRC report contains recommendations on (1) shortening the postdoctoral appointment, (2) reallocating NIH resources for postdoctoral support, (3) providing independent funding for postdocs, (4) clarifying the mentorship responsibilities of PIs, (4) broadening educational opportunities, (5) evaluating NIH postdoc programs, (6) establishing career transition research grants, (7) creating a new investigator RO1 grant, (8) supporting non-tenure track scientists, (9) providing a "safety net" for non-tenure track "soft-money" researchers, and (10) creating data collection systems on all NIH-supported researchers including postdocs, and staff scientists and other non-tenure-track researchers.

Thomas R. Cech, chairman of the NRC panel, said, "We think this is a an urgent matter. We do not think this is something that can last another five years. We think the vitality of the U. S. research enterprise in biomedical sciences depends on taking some action soon." (The *Chronicle of Higher Education* 4/1/05). Mr. Cech is president of the Howard Hughes Medical Institute.

The Sigma Xi report presents the results of a survey of working conditions of 7,600 postdocs in 46 institutions, mostly universities. Seventy percent of the postdocs reported overall satisfaction with their current experience, 22 percent were dissatisfied and 8 percent were neutral.

The study found that "postdocs reporting the greatest amount of structured oversight and formal training are much more likely to say they are satisfied, to give their advisors high ratings, to experience relatively few conflicts with their advisors and to be more productive in terms of number of publications compared with those with the least oversight and training."

The study suggested six components of effective structured oversight: (1) the postdoc received a letter of appointment or a contract that specified the advisor's responsibilities, (2) joint development of a plan by the postdoc and his or her advisor at the beginning of the appointment, (3) the research plan covered what the advisor would do, (4) the advisor provides the postdoc with formal performance evaluations, (5) the postdoc knew of a written policy addressing misconduct, and (6) the postdoc could transfer to a different research group if he or she desired.

The postdocs were generally satisfied with the informal and experiential education provided by their advisors, but advisors were not considered mentors by 24 percent of the postdocs. Sixty-two percent wanted formal training in proposal writing, and 40 percent or more wanted training in lab and project management, in writing, in teaching and in negotiating, the report states.

ORI Plans Exhibits at Scientific Meetings

ORI plans to hold exhibits at four scientific meetings this year to promote contact and generate dialogue with members of the biomedical and behavioral research communities.

Exhibits are planned for the following meetings:

- **American Society for Microbiology**, June 5-9, Atlanta.
- **American Sociological Association**, August 13-16, Philadelphia.
- **Association of Independent Research Institutes**, September 12-15, Washington.
- **Society for Neuroscience**, November 12-16, Washington.

ORI holds exhibits at scientific meetings to facilitate interaction between ORI staff and researchers, research administrators, postdocs, graduate students and institutional, association and society officials on the responsible conduct of research, the handling of research misconduct allegations, the sponsorship of conferences and workshops, the availability and creation of RCR instructional materials, and the ORI research programs.

Points for Discussion Offered on ORI Website

A new feature, Point for Discussion, has been added to the ORI home page to promote dialogue and debate related to the responsible conduct of research, research integrity, research misconduct and the organization of the research enterprise.

The points are quotations taken from journal articles, reports and other documents produced by scientific organizations, professional associations and government agencies.

The points are categorized under the following headings: research integrity, research misconduct, whistleblowing, self-regulation, institutional responsibilities, standards, research environment, collaborations, authorship, conflict of interest, mentoring, data management, peer review, and the role of scientists and scientific journals.

"The points for discussion are provocative and intellectually challenging," Larry Rhoades, Director, Division of Education and Integrity, said. "They provide a stimulating starting point for discussion, dialogue and debate in lab meetings, courses, workshops, and brown bag luncheons to explore the organization of the research enterprise as a coordinated human activity."

The Point for Discussion will be changed monthly, but individuals wishing to select their own topic can access all discussion points at *http://ori.hhs.gov/education/point_all.shtml*. Contributions to the collection of discussion points may be sent to *lrhoades@osophs.dhhs.gov*.

Ethical Issues In Animal Use

A report that seeks to clarify the ethical issues raised by the use of animals in research was published in May 2005 by the Nuffield Council on Bioethics in England. The report can be accessed through the ORI home page.

The report reviews the ways in which animals are used in different areas or research and makes recommendations for future policy and practices related to the use of genetically modified animals, the implementation of refinement, reduction and replacements, and the responsibilities of researchers, reviewers and funding bodies.

ORI Conferences - 2005

August 4-5 – Mentoring in Human Research Studies, Little Rock, AR

October 1 – Plagiarism Across the Science Disciplines: An Exploration of the Parameters of Plagiarism in Scholarly and Scientific Publications, New York, NY

October 7 – Promoting RCR in Research in the Social, Behavioral and Educational Sciences, San Antonio, TX

October 20-21 – Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID

Research Misconduct Investigations: Institutional Settings

Medical schools were the primary sites for research misconduct investigations from 1994-2003 by an overwhelming margin accounting for 72 percent of the investigations conducted.

A comparison of investigations occurring in the five-year periods 1994-1998 and 1999-2003 indicates that the institutional setting for investigations shifted substantially toward medical schools between the two periods from 65% to 82%, and away from other institutional settings.

In FY 2002, NIH awarded 50.6 percent of its extramural research funds to medical schools, 9.6 percent to research organizations, institutes, laboratories and foundations, 7.8 percent to independent hospitals, and 32.2 percent to other types of institutions.

Percent of Investigations and Research Misconduct Findings by Institutional Settings, 1994-2003*

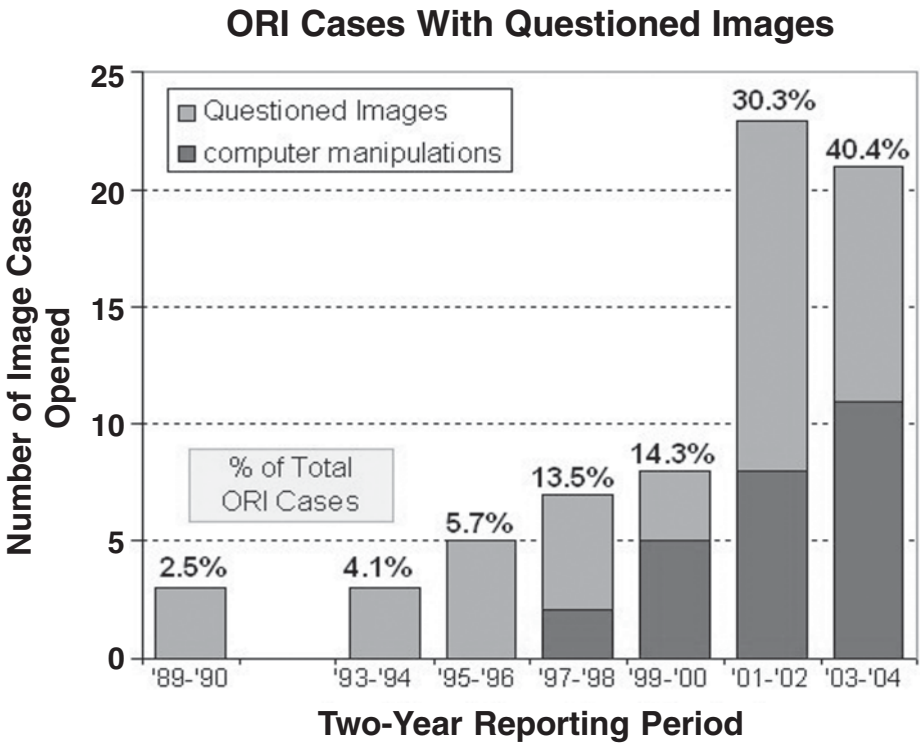
Setting	*Investigations*		*Misconduct Findings*	
	N	%	N	%
Medical Schools	187	72	90	68
Research Orgs., Institutes, Labs	27	10	14	10
Independent Hospitals	17	7	13	10
PHS Agencies	9	4	4	3
Other	19	7	12	9
TOTAL	259	100	133	100

*Only includes research misconduct investigations involving PHS supported research.

Confronting Manipulation of Digital Images in Science

John Krueger, ORI

Images have become a central currency in biomedical research. Digital technology has accommodated wondrously, with advances in data acquisition, with presentation software moving raw data effortlessly to reporting, and with an Internet enabling broad distribution, ready access, and archival retrieval. As exemplar data, scientific images have become more than a representation of qualitative results, especially when claimed to be the raw data - and more so when purported to be the origin of quantitative measurements and statistical tests, whether in blots, fluorescence co-localizations, or grain density in immuno-cytology. Falsification, fabrication, or plagiarism of an image in a thesis, a manuscript, in an article or its supplementary online file, can be scientific misconduct (See Case Summaries). The proverbial picture is worth a thousand words, but in science it can mean a career.



Growing Incidence of Digital Manipulation: ORI's case experience reflects the growing reliance of biomedical research on image data. Allegations involving images that met the test of both the definition of scientific misconduct and the jurisdiction of the PHS (42 C.F.R. 50) were a small part of ORI's early cases.(1) However, they have increased progressively, as have the number of cases involving manipulations by computer. The new-case history for the last four years indicates that special efforts are warranted to combat their incidence. (Bar Graph)

Multiple reasons for this trend doubtlessly exist, but two are obvious: "opportunity" and "detection." The ability to rapidly convert raw data into polished figures using photo-editing programs such as Photoshop®, and into a presentation using PowerPoint®, affords multiple opportunities, each spiced with temptation to make data look "better." The convenience in presentation also minimizes an avenue by which mentors formerly reviewed a student's data, *i.e.*, as when making each figure formerly required approval for spending funds on fiqure preparation. A modicum of mentorship can pay dividends, especially at the last and most pressured phases of a student's training.(1) Case incidence also reflects detection. In ORI's early cases, a problem image was rarely questioned because it appeared inauthentic,(1) but paradoxically the use of the same digital technology that provides opportunity makes the image manipulations easier to detect.

Prepublication Screening of Images by Journals: Leading journals are considering implementation of computerized screening to assess all images for overt signs of digital manipulation in manuscripts accepted for publication. One in particular has reported on its experience in the last two years, finding "approximately 20%" of the accepted articles had at least one figure showing "inappropriate manipulation," with a smaller but finite occurrence of images where it suspected the nature of the manipulations indicated a deliberate falsification, amounting to misconduct.(2) The latter figure is unreported,(2) but if it was only 1%, it would still be tenfold greater than ORI's total case load involving allegations of scientific misconduct of all forms. Unaccepted manuscripts were not examined.

Such "pre-publication" screening raises a host of practical and procedural questions: What detection methods can be implemented, are cost effective, and are uniformly accepted? What is the line between "inappropriate manipulation" and possible falsification, and what should be done in the latter case when a serious example of image manipulation is discovered? Should the editor "assess" the matter, or "investigate" more throughly? When and to whom should the matter be referred . . . the corresponding author, the author's institution, a funding agency? What technical resources or advice is available to assist in these matters?

Presentation Guidelines and Policies for Handling Questioned Images: Guidelines for the appropriate handling and presentation of digital images have been proposed (e.g., see Note 3). Having taken a lead in prepublication screening, the *Journal of Cell Biology (JCB)* was in a unique position to advance initial

Confronting Manipulation of Digital Images in Science *(from page 8)*

guidelines to assist authors in the accurate presentation of image data.[4, 5] Education about standards must keep abreast of technology. The *JCB* paper is now used as part of the required training in research ethics for intramural postdoctoral fellows at the National Institutes of Health.

From its experience *JCB* has also advanced the discussion of journal procedures for detection, assessment of manipulated images, and policy for disposition of allegations that arise in pre-publication screening.[4] Ideally, a broader discussion will occur, expanding to jointly serve the overlapping interest of the journals, the scientific community, and an accountability to the public that funds the research.

Forensic Tools and Education: When ORI gets an allegation of image falsification, an initial assessment is generally just a few keystrokes away. Images are published today online with sufficient quality that their authenticity can be tested using the same software used to create them. Typically such initial examinations involve computer visualization of otherwise imperceptible features of the image, morphological details, background detail and texture, *etc*., that are inconsistent with claims in the paper. Depending on their nature, visualization of such inconsistencies may require referral to the institution, where the original data are presumed to exist that will resolve the allegation.

Some simple and illustrative image processing routines, written as "Forensic Droplets" and "Forensic Actions" for Photoshop®, are now available at ORI's web site.[6] A "Droplet" in Photoshop® is a small desktop application that automatically processes image files dragged onto its icon. In use, while reading an article online, one simply drags the image from the Internet browser to the Droplet. The image will then be processed according to the selected Droplet. An "Action" in Photoshop® is simply the series of steps used to create the Droplet. Provision of the "Action" allows the user to modify the settings to examine the effects, to customize the forensic routines, or even to batch-process multiple images for screening. Presently requiring Photoshop® v.7, both tools are educational devices that can be used with an internet browser to effortlessly examine images in articles online or to study the incidence of manipulation. Their chief purpose is to promote awareness, but they may be useful to institutional committee members as possible investigative tools, to researchers interested in scrutinizing images, and for student instruction in research ethics training.

Advanced Techniques: ORI's methods simply visualize signs that an image is not authentic, based on an inconsistency with the claims about the experiment in the paper. However, computer scientists have described principles and developed tools that can detect intrinsic digital manipulations, *i.e.*, not based upon features that are perceptibly inauthentic to an expert in the area of research, but rather on the independent, statistical properties of the image itself.[7] Importantly, these tools also map the statistical alterations; and, as with ORI's methods, it is the pattern of what is revealed that is evidentiary.

Finally, scientific images—archived with sufficient resolution today—will be susceptible to novel scrutiny in perpetuity. Because authentication of a questioned scientific image requires the unreduced data, the refinement of tools for detection will also impose an additional incentive to retain the raw data. Additional education about presentation guidelines, knowledge about pre-publication screening by journals and the availability of detection tools and their use by their colleagues, may minimize the occurrence of falsified images in science or concerns about image data in the future.[8]

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6. http://ori.dhhs.gov/tools/data_imaging.shtml.
7. Alin C. Popescu and Hany Farid, "Statistical Tools for Digital Forensics," 6th International Workshop of Information Hiding. Toronto, CA 2004. http://www.cs.dartmouth.edu/~farid/publications/.
8. It will be instructive to see if the provision of tools to detect image manipulation has the same effect as have the online tools to detect plagiarism. The latter are credited with contributing to recent awareness of the problem and to the discussion of policies for detection. See Jim Giles, "Special Report, Taking on the cheats," *Nature* 435: 258-259, 2005.

Case Summaries

Jason W. Lilly, Ph.D., Boyce Thompson Institute: Based on the report of an investigation conducted by the Boyce Thompson Institute (BTI Report), the investigation report of another Federal agency, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Jason W. Lilly, Ph.D., postdoctoral fellow at BTI, engaged in scientific misconduct in research supported by the National Research Service Award, National Institutes of Health (NIH) postdoctoral fellowship, F32 GM64276. This case had been jointly handled by ORI and another Federal agency under the government-wide debarment regulations. Specifically, PHS found that:

A. Dr. Lilly falsified Figure 4, presenting a hierarchical cluster analysis of differential mRNA accumulation in cells grown in medium deficient in sulfate or phosphate in "*The Chlamydonomas reinhardtii* organellar genomes respond transcriptionally and post-transcriptionally to abiotic stimuli," *The Plant Cell* 14:2681:2706, 2002 (hereafter referred to as the Plant Cell paper) by claiming it was an average of three experiments when only one had been conducted;

B. Dr. Lilly further falsified Figure 4 of the *Plant Cell* paper by falsely coloring two cells in the blown-up portion of the figure that illustrated the induction of high levels of mRNA from the Sac1 gene;

C. Dr. Lilly falsified the supplemental gene array experiments published online claimed to be replicate assays by manipulation of both spreadsheet and image data from a single assay to make the altered data sufficiently different to appear to be separate assays;

D. Dr. Lilly falsified the text describing Figure 5 of the *Plant Cell* paper by claiming that the run-on assays had been replicated when they had not been;

E. Dr. Lilly falsified the purported replicates of run-on transcription experiments provided in the online supplemental material by manipulation of a single assay to make the variant versions appear different; and

F. Dr. Lilly falsified Figure 1 of the *Plant Cell* paper by using the same 16S control bands for RNA blots of two different genes (psbF and PsaG).

Dr. Lilly has been debarred by the lead agency for a period of two (2) years, beginning on March 4, 2005, and ending on March 4, 2007, and has entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he has voluntarily agreed: (1) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as consultant, for a period of four (4) years, beginning on April 18, 2005; and (2) that he will ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS funded research in which Dr. Lilly is involved, a certification that the data provided by Dr. Lilly are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report for a period of two (2) years, beginning on April 18, 2007, approximately corresponding to the termination date of the debarment period initiated by another Federal agency. Dr. Lilly must ensure that the institution also sends a copy of the certification to ORI.

Gary M. Kammer, M.D., Wake Forest University: Based on the Wake Forest University (WFU) Investigation Report, the respondent's admission, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Gary M. Kammer, M.D., former Professor, Division of Rheumatology, Department of Internal Medicine, and Department of Microbiology and Immunology at the WFU School of Medicine, engaged in scientific misconduct by falsification and fabrication of research in grant application 2 R01 AR39501-12A1, "T Lymphocyte Dysfunction in Lupus Erythematosus," submitted to the National Institute of Arthritis and Musculoskeletal Skin Diseases (NIAMS), National Institutes of Health (NIH), and in 1 R01 AI46526-01A2, "Protein Kinase A-II in the Pathogenesis of Lupus," submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. Specifically, PHS found that:

- the respondent fabricated Families 2 and 3 in Figure 6 and related text in application 2 R01 AR39501-12A1 (pp. 29-30), entitled "T Lymphocyte Dysfunction in Lupus Erythematosus") by:
  a. making up both of the pedigrees,
  b. fabricating 13 PKA-I and 13 PKA-II values for these nonexistent affected and unaffected family members, and
  c. composing the false text describing these two fabricated families.
- the respondent falsified the text describing the results in Figure 20

Case Summaries *(from page 10)*

("Inhibition of c-fos luciferase activity in S49 T cells transiently transfected with pIRES2-RIIb-EGFP and treated with 8-Cl-cAMP") in application 1 R01 AI46526-01A2 (p. 27), by falsely reporting N = 4, P less than 0.002, when the experiment had been performed only one time at the time that the application was submitted.

PHS also concluded that the respondent further demonstrated a lack of present responsibility as a Principal Investigator by submitting NIH grant proposals with additional unsupported experimental results:

- The pedigree and data for the family reported in grant application 2 R01 AR39501-12 and for Family 1 in grant application 2 R01 AR39501-12A1 are incorrect and the data pertaining to this family that Dr. Kammer subsequently provided to WFU after the inquiry were not the data reported in the applications. Dr. Kammer stated that he did not recall who in his laboratory gave him this pedigree. ORI noted that the actual PKA data for the "proof-of-principle" family, while suggesting that low PKA values may be hereditary (the presence of low PKA-I values in three generations), do not support the claims of the fabricated and mixed up pedigree and data that show that low PKA-I values were associated with Systematic Lupus Erythematosus (SLE) (application 2R01 AR39501-12).
- In application, R01 AI39501-12A1, the following unsupported statement was also included: "In both normal and disease controls, all Tcells express CD59+ and there is no significant difference in its cell surface expression on CD4+, CD45RA+, CD4+, CD45RO+, CD8+,CD45RA+, CD8+, CD45RO+ subsets (n=4 each control group; data not shown)." No data could be produced to support the information in the grant application about these control experiments.

Dr. Kammer has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on February 15, 2005: (1) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" as defined in the debarment regulations at 45 C.F.R. Part 76. This voluntary exclusion precludes the respondent from receiving Federal research, research training, or other research related funds from the Federal government for three (3) years, but shall not apply to the respondent's participation in a Federal health care program as defined in section 1128B(f) of the Social Security Act and shall not apply to Federal funds used solely for purposes of teaching or training medical students, residents, or fellows in clinical medical matters.

Anthropologist Resigns, Misconduct Found

An investigative panel at the University of Frankfurt concluded last February that the director of its Institute of Anthropology falsified data, plagiarized, and attempted to sell a collection of ape skulls owned by the university, according to *The Chronicle of Higher Education* (3/11/05).

Reiner Protsch von Zieten, a professor of anthropology, proclaimed his innocence, but resigned his position prior to the announcement of the findings. He said he had a right to sell the skulls.

Ulrich Brandt, chairman of the investigative panel, said colleagues questioned the data produced by Mr. Protsch von Zieten on many occasions over the years. "He always had an excuse," said Mr. Brandt. "If people asked to see the data, he would say it had been stolen, or there had been a fire. And it was too much effort for people to follow up on. They didn't realize he was doing it all the time."

When the criminal investigation into the sale of the skull collection is completed, a university disciplinary proceeding may be held university officials said. Possible sanctions include loss of his state pension and the title of professor.

Reporting Research Misconduct

"Members of the scientific community with knowledge of research misconduct have an ethical responsibility to come forward. But few are likely to fulfill this responsibility in the absence of a system that provided a fair review of concerns and effective protection from retaliation." *Report of the Commission on Research Integrity*, p. 21. Department of Health and Human Services. 1995.

Conference, Workshop, and Meeting Proposals Due October 1, 2005.

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to $20,000, depending on the event proposed.

The next target date for receipt of applications is **October 1, 2005**. Proposal instructions and an application form are available on the ORI web site at http://ori.hhs.gov/html/programs/confworkshops.asp. Please submit your proposal electronically to lrhoades@osophs.dhhs.gov. Call Dr. Larry Rhoades at 240-453-8400.

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